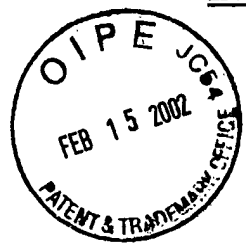


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2/28/02



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**RECEIVED**  
FEB 25 2002  
TECH CENTER 1600/2900

Applicants : Grimes and Blackburn  
Serial No. : 09/747,825  
Filed : December 22, 2000  
For : "STABLE IMMUNOGENIC  
COMPOSITION FO FROZEN STORAGE"  
Examiner : To be assigned  
Group Art Unit : 1645

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents Washington, D.C. 20231.	
Hans-Peter G. Hoffmann	37,352
Name	Reg. No.
	2-7-02
Signature	Date

Honorable Commissioner for Patents  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT  
BEFORE MAILING OF FIRST OFFICE ACTION**

Sir:

This communication and the attached Form PTO-1449 are submitted in compliance with  
37 C.F.R. §§1.56, 1.97 and 1.98. A copy of each of the documents listed on the Form PTO-1449  
is enclosed as part of this communication.

U.S. Patent No. 4,708,753 to Forsberg discloses a water-in-oil emulsion with a minor  
amount of emulsifying agent, wherein the oil phase is continuous. U.S. Patent No. 4,808,334 to

Ezaki, et al. is directed to a process for compositions which are sterilized at high temperature and emulsified. U.S. Patent No. 4,960,814 to Wu et al. discloses a process to prepare a water-in-oil emulsion or, more particularly, a water-in-hydrophobic polymer emulsion. Injectable water-in-oil vaccine emulsions of low reactogenicity containing Montanide ISA 703 with 1.8% AMS are disclosed in co-assigned U.S. Patents No. 5,023,077, 5,468,494 and No. 5,688,506. U.S. Patents No. 5,422,109 and No. 5,424,067 to Brancq, et al. disclose an injectable vaccine emulsion comprising a metabolizable oil. WO 90/14837 discloses an adjuvant composition where the emulsion droplets are submicron size. EP 0187286 describes stable oily adjuvant-emulsified vaccines composed of a paraffin oil, sorbitan monoleate and oxyethylene/oxypropylene polymer. U.S. Patent No. 5,376,369 to Allison, et al. discloses a vaccine adjuvant emulsion comprised of non-toxic polyols or oily block polymer in the presence of a potentiating muramyl dipeptide. U.S. Patent No. 5,679,355 to Alexander, et al. discloses vaccines containing non-ionic surfactant vesicles. U.S. Patent No. 5,109,026 to Hoskinson, et al. discloses vaccine formulations of water-in-oil emulsions containing polycationic polyelectrolyte immunoadjuvant and an oily substance, including, e.g., Drakeol, Markol, or any mixture of squalene and squalane. U.S. Patent No. 5,885,590 to Hunter et al. discloses injectable compositions of water-in-oil emulsions (and water-oil-water multiple emulsions) where the oily phase of the vaccine adjuvants can include squalene mostly with a lesser amount of squalane. U.S. Patent No. 4,350,605 to Hughett discloses emulsions with various stabilizers.

Consideration of each of the documents listed on Form PTO-1449 is requested.

Also enclosed is a copy of the International Search Report (ISR) received in the corresponding

PCT application. In addition, a copy of the above-identified international publication of the corresponding PCT application has been enclosed, as well as the copies of the references cited in the ISR.

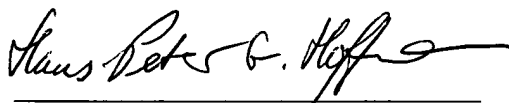
Applicant believes that the claimed frozen stable injectable immunogen composition is neither taught nor suggested by the prior art, as set forth above.

**TIME OF TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**

This Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits according to 37 C.F.R. §1.97(b)(3). Therefore, no fee is due in connection with this filing. However, should any fee be deemed necessary in connection with this filing, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 23-1703.

Dated: February 7, 2002

Respectfully submitted,



Hans-Peter G. Hoffmann, Ph.D.

Reg. No. 37,352

Agent for Applicant

Customer No. 007470

Agent's Direct Dial: (212) 819-8840

Enclosure